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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,773	07/28/2003	Norbert W. Bischofberger	234.PC2	5777

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/628,773	Applicant(s) BISCHOFBERGER ET AL.	
	Examiner Shobha Kantamneni	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a CON of 09/153,964, filed on 09/16/1998 ABN, which claims benefit of 60/060,195 filed on 09/26/1997, and 60/059,308 filed on 09/17/1997.

Claims 1-13 are pending.

Election/Restrictions

Claims 11-13 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election without traverse of invention Group I, claims 1-10 drawn to a pharmaceutical formulation comprising an enteric protectant, and a compound of formula as in claim 1 is acknowledged.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

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claims. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is therefore made FINAL.

Claims 1-10 are examined herein as they read on the elected invention.

Information Disclosure Statement

The information disclosure statement filed 07/28/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but some of the non-patent literature publication referred to therein has not been considered. Note that the non-patent literature publications not supplied with the instant application, and not cited in the prior application 09/153,964 have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-4, 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischofberger et al. (US 5,763,483, PTO-1449), in view of Remington Pharmaceutical Sciences (17 ed, Gennaro et al Ed., Mack Publ, 1985, PTO-1449), and Eisenberg et al. (Antimicrobial Agents and Chemotherapy, 1997, Vol. 41(9), pages 1949-1952).

Bischofberger et al. disclose pharmaceutical formulations comprising compound of the formula as in instant claim 1. See column 3, line 49-column 4, line 11; column 70, compound 228; column 134, embodiment 15; and column 143-144, claims 1-3. It is also disclosed that the compositions can comprise salts of the compounds formed from acid addition of organic or inorganic acids, e.g., HCl, HBr, H₂SO₄, or organic sulfonic acids to basic centers such as amines. See column 32, lines 57-63. The formulations containing the compounds can be prepared by any methods well known in the art of pharmacy such as those in Remington's Pharmaceutical Sciences. See column 35, lines 12-18. The compositions can be in the form of tablets, capsules, solutions, suspensions etc. See column 35, lines 25-33. The tablets can be optionally coated or scored to provide slow release of the active ingredient. See column 35, lines 42-44. It is also disclosed the composition are used in a method of inhibiting the activity of neuraminidase. See abstract.

Bischofberger et al. does not explicitly teach the pharmaceutical formulation comprising an enteric protectant.

Remington's Pharmaceutical Sciences teaches that film coatings can be applied to pharmaceutical products in order to modify the release pattern of a drug. It is also taught that one form of coating is to protect drugs from the effects of the gastric

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environment such as enteric coating which remain intact in the stomach, but will dissolve and release the contents of the dosage form once they arrive at the small intestine. It is also taught that the most extensively used polymer as an enteric coating protectant is cellulose acetate phthalate (CAP). See page 1637.

Eisenberg discloses instant claimed compound [(3R, 4R, 5S)-4-acetamido-5-amino-3-(1-ethyl-propoxy)-1-cyclohexene-1-carboxylic acid], GS 4071 as a potent and selective inhibitor of influenza viral neuraminidase. Eisenberg et al. further discloses instant claimed compound an ethyl ester i.e compound as in claim 4 gets absorbed "from the gastrointestinal tract", and gets converted to the active form GS4071. See abstract; page 1949, left hand, paragraph 3.

From the teachings of Remington's pharmaceutical sciences, it would have been obvious to a person of ordinary skill in the art at the time of invention to teach the pharmaceutical formulation of Bischofberger as comprising an enteric protectant.

One of ordinary skill in the art at the time of art would have been motivated to teach the formulations of Bischofberger et al. as comprising an enteric protectant because Remington teaches that it is well known in the pharmaceutical art to use enteric coating protectant such as cellulose acetate phthalate to modify the release pattern of a drug.

Further, one of ordinary skill in the art at the time of invention would have been motivated to formulate the composition of Bischofberger comprising an enteric protectant with the expectation of obtaining a formulation which is stable towards the acidic environment in the stomach, but will get absorbed from the gastrointestinal tract

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and release the active contents because Eisenberg et al. teach absorption of the ester of compound [(3R, 4R, 5S)-4-acetamido-5-amino-3-(1-ethyl-propoxy)-1-cyclohexene-1-carboxylic acid] from the gastrointestinal tract, as opposed to the stomach.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kent et al (US 5, 859, 284, PTO-1449), in view of Remington Pharmaceutical Sciences (17 ed, Gennaro et al Ed., Mack Publ, 1985, PTO-1449), and Eisenberg et al. (Antimicrobial Agents and Chemotherapy, 1997, Vol. 41(9), pages 1949-1952).

Kent et al. disclose compositions comprising compound of the instant formula as in claims 1, and claim 4. See column 23, compound 116. It is also disclosed that the compositions can comprise salts of the compounds formed from acid addition of organic or inorganic acids, e.g., HCl, HBr, H₂SO₄, H₃PO₄ or organic sulfonic acids to basic centers such as amines. See column 27, lines 28-31; see column 31, Example 12 wherein a phosphate salt is disclosed. It is also disclosed the composition are used in a method of inhibiting the activity of neuraminidase. See abstract.

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Kent et al. does not explicitly teach the pharmaceutical formulation comprising an enteric protectant.

Remington's Pharmaceutical Sciences teaches that film coatings can be applied to pharmaceutical products in order to modify the release pattern of a drug. It is also taught that one form of coating is to protect drugs from the effects of the gastric environment such as enteric coating which remain intact in the stomach, but will dissolve and release the contents of the dosage form once they arrive at the small intestine. It is also taught that the most extensively used polymer as an enteric coating protectant is cellulose acetate phthalate (CAP). See page 1637.

Eisenberg discloses instant claimed compound [(3R, 4R, 5S)-4-acetamido-5-amino-3-(1-ethyl-propoxy)-1-cyclohexene-1-carboxylic acid], GS 4071 as a potent and selective inhibitor of influenza viral neuraminidase. Eisenberg et al. further discloses instant claimed compound an ethyl ester i.e compound as in claim 4 gets absorbed "from the gastrointestinal tract", and gets converted to the active form GS4071. See abstract; page 1949, left hand, paragraph 3.

From the teachings of Remington's pharmaceutical sciences, it would have been obvious to a person of ordinary skill in the art at the time of invention to teach the pharmaceutical formulation of Kent et al. as comprising an enteric protectant.

One of ordinary skill in the art at the time of art would have been motivated to teach the formulations of Kent et al. as comprising an enteric protectant because Remington teaches that it is well known in the pharmaceutical art to use enteric coating protectant such as cellulose acetate phthalate to modify the release pattern of a drug.

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Further, one of ordinary skill in the art at the time of invention would have been motivated to formulate the composition of Kent comprising an enteric protectant with the expectation of obtaining a formulation which is stable towards the acidic environment in the stomach, but will get absorbed from the gastrointestinal tract and release the active contents because Eisenberg et al. teach absorption of the ester of [(3R, 4R, 5S)-4-acetamido-5-amino-3-(1-ethyl-propoxy)-1-cyclohexene-1-carboxylic acid] from the gastrointestinal tract, as opposed to the stomach.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Shobha Kantamneni
Patent Examiner
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SHENGJUN WANG
PRIMARY EXAMINER